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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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EXAMINER	
LEFFERS JR.G	
ART UNIT	**PAPER NUMBER**
1636	15

DATE MAILED: 02/14/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/359,300	Kumagai, et al.
Examiner	**Group Art Unit**
Gerald G. Leffers Jr.	1636

X Responsive to communication(s) filed on *Nov 27, 2000*.

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *three* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

X Claim(s) *45-70* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

Claim(s) _____ is/are allowed.

X Claim(s) *45-70* is/are rejected.

Claim(s) _____ is/are objected to.

Claims _____ are subject to restriction or election requirement.

Application Papers

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on _____ is/are objected to by the Examiner.

The proposed drawing correction, filed on _____ is approved disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All Some* None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) _____.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

Notice of References Cited, PTO-892

X Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- *SEE OFFICE ACTION ON THE FOLLOWING PAGES* ---

DETAILED ACTION

Receipt is acknowledged of applicants amendments mailed 9/26/00 and 11/27/00. The amendment mailed 9/26/00 amended claim 45 and added new claims 46-56. The amendment filed 11/27/00 modified claim 45 a second time as well as presented a new set of claims numbered 46-59. This was done without indicating that the additional claims from 46-59 were modifications of the claims added in the 9/26/00 amendment. Consequently, the claims added as part of the 11/27/00 amendment have been renumbered to begin with the next available claim number (i.e. 57-70).

Receipt is acknowledged of applicants' amendment to the specification filed 9/26/00 in which a new copy of the paper sequence listing, CRF and corresponding attorney's statement were submitted. The paper copy of the sequence listing and attorney statement have been entered into the file. Applicant is hereby notified that the CRF was entered into the database following correction by STIC of the CPS designator for SEQ ID NOS: 9 and 50.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The following rejections are maintained for reasons of record in Paper No. 5, mailed 4/26/00.

Claim 45 of this application conflicts with claim 43 of Application No. 09/359,297 and with claim 43 of Application No. 09/359,305. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claim 45 is provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 43 of copending Application No. 09/359,297. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 45 of the instant application is an obvious variation of the method of claim 43 in Application No. 09/359,297. Claim 43 of Application No. 09/359,297 specifies that the nucleic acids (derived from any donor) are oriented, depending on how the claim is read (see below), either all in a positive sense orientation, negative sense orientation or a mixture of both orientations within the pool of nucleic acids expressed in the

plant host. It is and was well known in the art at the time the invention was made that expression of DNAs, in either orientation, having homology to endogenous plant genes may result in phenotypic changes due to alteration of the expression of the host gene. Claim 45 of the instant specification merely specifies that all of the donor nucleic acids be oriented in a single, positive sense orientation.

Likewise, claim 45 is also provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 43 of copending Application No. 09/359,305. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of claim 45 of the instant application is an obvious variation of the method of claim 43 in Application No. 09/359,305. Both claims are directed towards a screening method in which heterologous nucleic acids are expressed in a plant host and any detectable biochemical or phenotypic change is associated with expression of a particular donor nucleic acid. It is and was well known in the art at the time the invention was made that expression of DNAs in a positive sense orientation which have homology to endogenous plant genes may result in phenotypic changes due to alteration of the expression of the host gene. Claim 45 of the instant application specifies that any organism can serve a the donor whereas claim 43 of Application No. 09/359,305 merely limits the donor organisms to plants.

These are provisional obviousness-type double patenting rejections because the conflicting claims have not in fact been patented.

Response to Arguments

Applicants response mailed 9/26/00 states that applicants will address the outstanding double patenting rejections upon indication of allowable subject matter in the instant application.

The following is a new rejection.

Claims 32-70 of this application conflict with claims 41, 43-45 and 57 of Application No. 09/359,301. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

Claims 32-45 of the instant specification are drawn towards expression of nucleic acids from an organism in a positive sense orientation in plants in order to obtain a functional profile. Claims 41, 43-45 and 57 are drawn to methods of compiling a plant functional gene profile with donor plant nucleic acids. Thus, claims 32-45 of the instant application broader in scope and totally encompass those of claims 41, 43-45 and 57 of the '305 application. If a patent were to issue for each set of claims, the patent issuing on the instant claims would potentially extend protection for the claims of the '305 application featuring a plant donor as well as providing protection for embodiments wherein the donor is not a plant. Also, if a patent issued on the

instant application were to be transferred to an assignee different from an assignee holding a patent issued on claims 41, 43-45 and 47 of the '305 application, two different assignees would hold a patent to the issued claims from the '305 application. Thus, improperly, there would be possible harassment by multiple assignees. *see* Eli Lilly & Co. vs. Barr Laboratories 55USPQ2d 1609

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 45-70 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 45 and 57 are vague and indefinite in that there is no clear and positive prior antecedent basis for the term "said one or more changes" in step (f) of each claim.

Claims 45 and 57 are vague and indefinite in that the metes and bounds of the phrase "..identifying a trait associated with said one or more phenotypic or biochemical changes.." are unclear. **This rejection is necessitated by applicants' amendment filed 9/26/00.** The term "trait associated with a biochemical or phenotypic change" does not appear to be well defined in the specification. What exactly is an "associated trait" in this instance and how does it differ

from the biochemical or phenotypic change specified in the definition for a "functional gene profile"? How directly does the "associated trait" have to be associated with the biochemical or phenotypic change in order to satisfy the claim limitation? Does it have to be a function associated with a protein encoded by a nucleic acid homologous to the heterologous nucleic acid expressed in the plant host cell? It would be remedial to amend the claim language to clearly indicate what is intended by the term "associated trait" and how it differs from the biochemical or phenotypic change with which it is associated.

Response to Arguments

In response to a similar rejection of claim 45 applicants amended the specification from "an associated trait where a phenotypic or biochemical change occurs" by reversing the orientation of the associated trait and the phenotypic/biochemical change in the claim language. Contrary to the assertion in applicants response of 9/26/00, this change does not clarify the relationship between the "associated" trait and the biochemical or phenotypic change with which it is associated. In the supplemental response filed 11/27/00 it is asserted that there may be many different phenotypic or biochemical changes associated with one trait. When steps b) - f) are repeated, changes related to the same trait are selected and grouped.

This is actually inaccurate for claims 45 and 57 in that the step of determining a trait associated with the biochemical or phenotypic change is repeated until a nucleic acid is selected which is associated with a trait. Which trait is the unidentified nucleic acid to be associated with, the first associated with a biochemical or phenotypic change, or one associated with a second set

of phenotypic or biochemical changes, etc.? Once a set of biochemical or phenotypic changes are chosen in the first cycle, are subsequent different phenotypic/biochemical changes identified for subsequent rounds of identification? Finally, the metes and bounds of the relationship between the phenotypic or biochemical changes and an associated trait are not clear. It remains unclear from the claim language and the specification, how does a trait differ from a biochemical or phenotypic change?

As noted above, claims 45 and 57 are vague and indefinite in that there is no clear and positive prior antecedent basis for the term "said trait" in line two of step (g) claim for 45, or in line two of step (h) of claim 57. Which associated trait is specified, the first or second or third trait observed with the biochemical or phenotypic change following expression of an unidentified nucleic acid.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 57-70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants' amendment filed 11/27/00.**

The rejected claims are all directed towards methods of compiling a positive sense functional gene profile of an organism comprising preparing a library of unidentified nucleic acids, constructing a viral vector(s) comprising the unidentified nucleic acids followed by transient expression in a plant host, identification of a biochemical or phenotypic change, identifying a phenotypic change associated with the biochemical or phenotypic trait and the nucleic acid orientation is only determined or selected following identification of the nucleic acid associated with the observed trait. There does not appear to be support in the specification as filed for the specific limitation of determining the positive sense orientation of an unidentified nucleic acid following the determination of a trait associated with biochemical or phenotypic change upon expression of the unidentified nucleic acid. Therefore, this limitation is considered to be NEW MATTER.

Claims 45-70 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new rejection necessitated by applicants amendment filed 9/26/00.**

Each of the rejected claims comprises the following limitation: "..until at least one nucleic acid associated with said trait is identified, whereby a positive sense functional gene profile of said plant host or said donor organism is compiled.". There does not appear to be

support anywhere in the specification for the specific limitation of the criteria for establishment of a functional gene profile being met after at least one nucleic acid associated with a trait has been identified. Therefore, this limitation is deemed to constitute NEW MATTER.

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers, Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on Monday through Friday, from about 8:00 AM to about 4:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott, can be reached on (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

G. Leffers, Jr.

Patent Examiner

Art Unit 1636

DAVID GUZO
PRIMARY EXAMINER

February 12, 2001